

## New Evidence of Strong Public Support for Federal Spending for Cancer Research

BY PEGGY EASTMAN

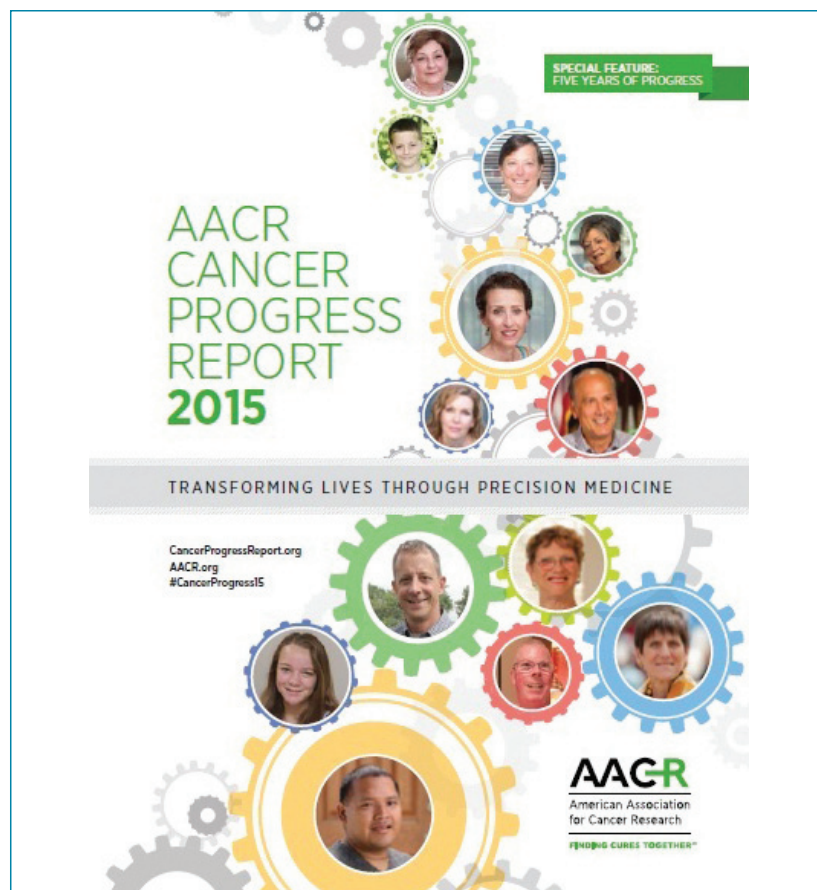
**A** new survey from the American Association for Cancer Research, released in conjunction with the organization's fifth annual Cancer Progress Report to Congress, shows that 74 percent of American voters support increased federal expenditures for cancer research. Nearly half (49%) are strongly in favor of that increase.

In an interview, AACR President José Baselga, MD, PhD, Physician-in-Chief at Memorial Sloan Kettering Cancer Center, said he was very encouraged that the American public feels so strongly about the need for increased federal cancer research funding (*see article on page 20*).

The survey shows that by a margin of five to one, voters say they would be more likely to vote for a Presidential candidate who supports making cancer research a national priority through sustained increases in federal expenditures.

The results indicate that overall, nearly 70 percent of Americans consider increased funding for medical research on cancer, heart disease, and Alzheimer's disease to be a high priority for Congress. That figure is on a par with the percentage who want increased funding for public education.

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## AML/MDS Outpatient Care Post-Induction

BY ROBERT H. CARLSON

**A** significant portion of the cost of treating adults with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) comes from lengthy hospitalizations until blood cell count recovery after induction or salvage chemotherapy. But early discharge of these patients using intensive outpatient support may be a safe way to reduce those costs, according to authors of a small Phase II study from the University of Washington Fred Hutchinson Cancer Research Center.



The non-randomized single-center study—online ahead of print in the *JAMA Oncology* ([doi:10.1001/jamaoncol.2015.2969](https://doi.org/10.1001/jamaoncol.2015.2969))—compared safety, resource utilization, infections, and costs for 107 adults discharged early following AML or MDS induction or salvage therapy versus inpatient controls for 29 patients receiving the same treatment.

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## New Options for Patients with Advanced RCC

BY ED SUSMAN

**V**IENNA, Austria—A pair of studies indicate that two new drugs can significantly extend both overall and progression-free survival among patients with advanced renal cell carcinoma, researchers reported here at

the European Cancer Congress. Patients treated with nivolumab achieved a median overall survival of 25 months compared with 19.6 months with everolimus, said Padmanee Sharma, MD, PhD, Professor of Genitourinary Medical Oncology and

Immunology at the University of Texas MD Anderson Cancer Center.



“The risk of death was reduced by 27 percent in patients in the nivolumab-treatment group compared with those in the everolimus group,” she said at a news conference sponsored by the meeting organizers. In the Bristol-Myers Squibb-sponsored CheckMate 025 study, 21 percent of the patients on nivolumab achieved an objective response to therapy—including four patients who had a complete response—compared with five percent of patients receiving everolimus. (Everolimus is the current standard of care for patients with metastatic renal cell carcinoma.)


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### FDA Actions



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# AACR SURVEY & CANCER PROGRESS REPORT *Continued from page 1*

The percentage of people urging federal support for cancer research funding is even higher than that for those supporting increased funding for military and veterans (68%); reductions in student debt/more affordable college costs (61%); and funding for road and highway improvements (56%).

The survey was conducted this summer (July 25 to 29), among a national cross-section of 1,000 registered U.S. voters, by Hart Research Associates and Public Opinion Strategies. The interviews were done via telephone, and included landlines, cell phones, and VOIP connections.

## Reducing National Debt and Federal Spending

The new survey data reveal that American voters want higher federal funding for biomedical research despite the fact that 75 percent of survey respondents also consider reducing the national debt and federal spending to be a high priority for Congress.

The results also showed that 85 percent of American voters recognize that progress is being made against cancer. Respondents of all ages also said that among diseases and major health conditions, cancer was what they were most worried about developing (ahead of Alzheimer's disease, heart disease, diabetes, obesity, and HIV/AIDS).

## Call for 7% Increase for NIH

Armed with these new survey data, AACR has issued a call to action to Congress and the administration to implement a strategy of providing annual

federal budget increases of at least seven percent for the National Institutes of Health, National Cancer Institute, and the Food and Drug Administration beginning in fiscal year 2016.

"There is no time to waste when, in the United States alone, we are losing one person every minute of every day to the devastating collection of diseases we call cancer," Baselga said in the introduction to the report, co-written with AACR CEO Margaret Foti, PhD.

## 'Unwavering Bipartisan Support'

The AACR 2015 Progress Report shows that the U.S. five-year survival rate for all cancers combined increased from 49 percent in the mid-1970s to 68 percent in 2010, with 14.5 million cancer survivors alive today.

"The Progress against cancer highlighted in the report underscores how unwavering, bipartisan support from Congress and the administration, in the form of sustained increases in funding for the NIH, NCI, and FDA, are vital if we are to continue to make progress for the benefit of families everywhere," Baselga said in the executive summary of the report.

The clear message of the survey, he said, is that the American people have the same message for Congress as the AACR does: increased funding for cancer research needs to be a national priority.

## High Costs, High Toll of Suffering

The report notes that cancer is a costly disease that exerts an economic burden on society as well as a high

toll of suffering on patients and their families, and that research is a vital investment to reduce that economic burden.

In the United States, the estimated direct medical costs of cancer care in 2010 were \$125 billion; these costs will likely rise to \$156 billion in 2020, according to statistics cited in the report.

"These costs stand in stark contrast to the NIH budget for fiscal year (FY) 2015, which is \$30.3 billion," the AACR document states. They stand in even starker contrast to the total National Cancer Institute budget for fiscal year 2015, which is just \$5 billion. The aging of the population, coupled with the fact that almost 70 percent of U.S. cancer cases are diagnosed in people age 55 and older, means that cancer incidence will likely continue to rise.

## Specific Advances

The progress report notes the encouraging recent advances of the following FDA approvals between August 2014 and July 31, 2015:

- Nine new anti-cancer therapies;
  - New uses for six previously approved anticancer therapies;
  - A new use for an imaging agent;
  - A new cancer screening test; and
  - A new cancer prevention agent.
- Specifically, drugs included in the advances mentioned in the 2015 report are:
- The angiogenesis inhibitors bevacizumab, lenvatinib, and ramucirumab;
  - The bone-remodeling inhibitor denosumab;
  - The cell-signaling inhibitors gefitinib, ibrutinib, palbociclib, and sonidegib;
  - The DNA repair inhibitor olaparib;

## AMERICAN ASSOCIATION FOR CANCER RESEARCH SURVEY ON CANCER AND CANCER RESEARCH FUNDING\*



Increasing funding for medical research is among American voters' top priorities for Congress.

74%

of American voters favor increasing federal funding for cancer research.

81%

of American voters favor using taxpayer dollars to fund medical research; this support is bipartisan.



BY 5 TO 1

voters are more likely to vote for a presidential candidate who supports making the fight against cancer a national priority by providing sustained increases in federal funding for cancer research.



Voters are also more likely to vote for a Congressional candidate who supports sustained increases in federal funding for cancer research.

\*Survey conducted on behalf of the AACR by Hart Research Associates and Public Opinion Strategies



## FDA Priority Review Status for Defibrotide and Halaven

The U.S. Food and Drug Administration has given priority review designations to the following:

- Defibrotide for the treatment of patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome or SOS) with evidence of multi-organ dysfunction following hematopoietic stem-cell transplantation (HSCT) and;
- Halaven (eribulin mesylate; also known as eribulin) for the treatment of patients with inoperable soft tissue sarcoma (leiomyosarcoma and liposarcoma) who have received prior chemotherapy for advanced or metastatic disease.

The FDA's priority review designation shortens the time to complete a drug's review and aims to deliver a decision on marketing approval designation for drugs that may offer major advances in treatment or provide a treatment where no adequate therapy exists within six months under

the Prescription Drug User Fee Act (PDUFA).

### Defibrotide

Defibrotide, marketed by Jazz Pharmaceuticals, is an oligonucleotide with a mechanism of action that encompasses both restoration of the thrombo-fibrinolytic balance and endothelial cell protection. The FDA action date for defibrotide for this indication is March 31.

The product had previously been granted both Orphan Drug and Fast Track status. In addition, defibrotide is being made available as an investigational new drug (IND) free of charge through an expanded access Treatment Protocol, which is currently enrolling patients diagnosed with VOD in the United States.



### Halaven

Halaven, marketed by Eisai, is a microtubule dynamics inhibitor that exerts its ef-

fects via a tubulin-based antimitotic mechanism ultimately leading to apoptotic cell death after prolonged and irreversible mitotic blockage. The FDA action date for Halaven for this indication is January 29.

Approval for defibrotide will be based on the safety and efficacy data from three clinical studies of patients with hepatic VOD with multi-organ dysfunction following HSCT, as well as a retrospective review of registry data from the Center for International Blood and Marrow Transplant Research. The safety database includes more than 900 patients exposed to defibrotide in the clinical development program for the treatment of hepatic VOD.

Halaven has previously been approved for the treatment of patients with metastatic breast cancer who have received at least two chemotherapeutic regimens for the treatment of metastatic disease, and whose prior therapy included an anthracycline and a taxane in either the adjuvant or metastatic setting.

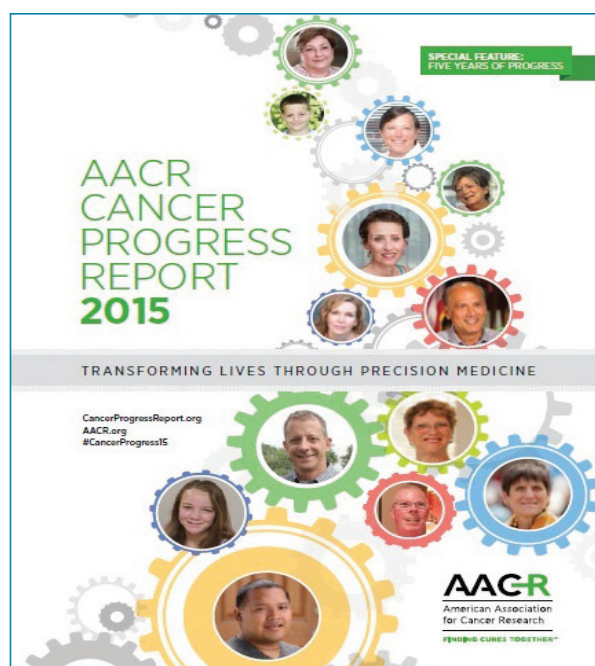
Halaven's approval for this indication in sarcoma will be based on data from a Phase III clinical trial of 452 patients with high- or medium-grade liposarcoma or leiomyosarcoma who had previously undergone at least two anti-cancer regimens who were assigned to receive either Halaven or dacarbazine.

The data—which were presented at this year's American Society of Clinical Oncology Annual Meeting—showed that patients receiving Halaven had a median overall survival of 13.5 months compared with 11.5 months for patients receiving dacarbazine (*OT 6/25/15 issue*). □

## AACR Survey

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- The epigenome-modifying agent panobinostat;
- The immunotherapies blinatumomab, dinutuximab, nivolumab, and pembrolizumab;
- The imaging agent technetium 99m tilmanocept (for lymphatic mapping in solid tumors);
- The cancer screening test Cologuard (for colorectal cancer); and
- The preventive vaccine human papillomavirus 9-valent vaccine (types 6, 11, 16, 18, 31, 33, 45, 52 and 58) for cervical, vulvar, vaginal, and anal cancers.



## Four Immunotherapies

The four immunotherapies approved by the FDA during the same period represent the largest number of immunotherapeutic agents approved in a 12-month period since the first AACR Cancer Progress Report was published in 2011, the new report states—"highlighting how this powerful form of cancer treatment has emerged as a key pillar of cancer care."

## Precision Medicine

The report, which features the stories of 13 cancer patients, hails the promise of

precision medicine, noting that increasingly, anticancer therapies are precisely targeted against factors responsible for the cancer, thus reducing harm to normal cells.

"Although precision medicine is not unique to the practice of oncology, oncology is leading such efforts largely because of our immense knowledge of the role of genetic mutations in the development and progression of cancer," the AACR document says. "As we look to the future, the pace of progress in precision medicine will continue to accelerate."

## Rally for Medical Research

In conjunction with the release of its report, AACR held a Congressional briefing and reception to celebrate the contributions of medical research and highlight the need for Congress to support a strong, sustained funding stream for cancer research. The Senate NIH Caucus, led by Senators Dick Durbin (D-IL) and Lindsey Graham (R-SC), was an honorary sponsor.

AACR also sponsored a breakfast and Rally for Medical Research Hill Day featuring members of Congress, AACR CEO Foti, and Sue Peschin, CEO of the

Alliance for Aging Research, among many others. During the Hill Day, hundreds converged on Capitol Hill for meetings with House and Senate staffers to make the case for "robust, sustained, and predictable" funding increases for cancer research for 2016 and beyond (*read more about it on page 40*).

AACR, the founding organizer, partnered with some 300 organizations across the country to spread the message about stronger support for biomedical research; this was the third such event that has been held in Washington. □